

Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising

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BYPASSING THE LEARNED INTERMEDIARY: POTENTIAL LIABILITY FOR FAILURE TO WARN IN DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING

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INTRODUCTION

Direct-to-consumer advertising¹ is one of the most significant recent developments in the marketing of prescription drugs, potentially opening vast new markets for advertisers and introducing innovative products to potential patients otherwise unaware of recent developments. The rise of direct-to-consumer advertising also raises new problems; specifically, how to regulate the flow of information to patients through advertising.

Direct-to-consumer advertising undermines the traditional legal rules governing transmission of information to patients. Current FDA regulations require drug manufacturers to provide information and warnings directed at the prescribing physician,² who in turn must warn the patient under common law tort doctrine. A drug manufacturer is generally not liable for failing to directly warn the consumer of potential adverse consequences of prescribed drugs.³ This "learned intermediary" rule follows from the assumption that the prescribing physician is best able to properly communicate the relevant risks to the patient and most able to understand a complex warning when deciding whether the stated risks outweigh the benefits for a particular patient.

When drug manufacturers advertise directly to consumers, they bypass the intermediary assumed by the traditional legal duties. The drug company has no duty under current regulations to provide a warning tailored to the consumer. The required physician-directed warnings are too complex to efficiently educate consumers. Further, the doctor must deal with an unknown source of information. The doctor will find it commensurately harder to educate patients with preconceived expectations about a treatment gained from direct-to-consumer advertisements.

This article examines current tort doctrine and FDA regulation relevant to direct-to-consumer prescription drug advertising and draws three conclusions. First, although the FDA has the statutory and constitutional authority to regulate this practice, it has not done so to date, relying instead on regulations

¹ Throughout this article, the term "direct-to-consumer advertising" will refer to direct-to-consumer advertising of prescription drugs. Advertising of over-the-counter drugs is beyond the scope of this article.

² See *infra* note 50 and accompanying text.

³ RESTATEMENT (SECOND) OF TORTS § 402A (1965).

designed to police advertising directed to health-care professionals.

Second, these current regulations are inadequate to cope with the issues raised by direct-to-consumer advertising. Specifically, they present no workable solution to the potential problem of informed consent, nor do they provide a uniform framework for realistic depictions of a drug's benefits and dangers to a lay audience.

Third, until such time as the FDA explicitly acts to occupy this area, or until Congress states an intent to preempt concurrent state tort regulation, state tort laws are not preempted from regulating direct-to-consumer prescription drug advertising. Indeed, state tort law, in the absence of explicit federal regulation tailored to direct-to-consumer advertising, should be used to police direct-to-consumer prescription drug advertising. State courts can provide a level of review that is lacking in agency procedure at the federal level and protect individual consumers from overreaching by drug companies and from mistakes by the FDA.

I. A BRIEF HISTORY OF DIRECT-TO-CONSUMER ADVERTISING

In the mid-1980's, previously firm opposition to direct-to-consumer advertising among medical professionals,⁴ regulators, and even the public began to ebb.⁵ Pressure on the FDA to change its policy of opposition to direct-to-consumer advertising resulted in 1985 in FDA action lifting the moratorium.⁶ Early advertising campaigns were not

⁴ The American Medical Association held out longer than other groups in its opposition to direct-to-consumer advertising, but even the AMA has recently lifted its official opposition to direct-to-consumer advertising, subject to two conditions. First, the ad in question must have "educational value," and second, drug manufacturers must provide "physician education materials." *AMA Overturns Long-Standing Direct-to-Consumer Rx Ad Ban, Providing Ads Have "Education" Value and Physician Education Materials Are Made Available*, FOOD DRUG COSM. REP. PRESCRIPTION AND OTC PHARMACEUTICALS (THE PINK SHEET), June 29, 1992, at 3; Patricia Winters, *Prescription Drug Ads Up*, ADVERTISING AGE, Jan. 18, 1993, at 10.

⁵ See Louis A. Morris et al., *The Attitudes of Consumers Toward Direct Advertising of Prescription Drugs*, PUB. HEALTH REP., Jan.-Feb. 1986, at 82.

⁶ See Merrell Dow Planning Rx Direct Consumer Ads in Wake of FDA Decision Sept. 9 to Lift Voluntary Moratorium, FOOD DRUG COSM. REP. PRESCRIPTION AND OTC PHARMACEUTICALS (THE PINK SHEET), Sept. 16, 1985,

product-specific, but were more purely "informative." They were designed to heighten public awareness of a health "problem" and encourage potential patients to consult a doctor.⁷ Of course, the most vocal proponents of this form of advertising are those companies with market dominance in a given category of drug, since they are likely to reap the lion's share of the rewards.⁸ For example, if a company has a seventy percent market share in a category, it will likely receive the same percentage of new prescriptions resulting from a non-product-specific ad campaign, no matter who actually pays for the advertisements.

Upjohn Company was the first manufacturer to use product-specific direct-to-consumer advertising in the U.S. for promoting its hair-loss treatment, Rogaine.⁹ This product was, in hindsight, probably the ideal test case for direct-to-consumer advertising, at least from a products liability perspective. Although a prescription drug, Rogaine is in many ways a cosmetic product, easily analogized to the birth control exception to the learned intermediary rule.¹⁰ The decision to use the product is likely to be discretionary, not fueled by medical necessity. A doctor need only be consulted to determine initial eligibility for the treatment and to facilitate purchase of the drug. In addition, the chances of severe injury resulting from use of the product are low.¹¹ Thus, the damage element of any

at 3.

⁷ See, e.g., Advertisement by Merck describing the prostate, its functions, and the symptoms of prostate enlargement, *TIME*, Jan. 25, 1993, at 20-21.

⁸ In 1992, Merck Co., following the introduction of Proscar, a "ground-breaking" new prostate cancer treatment, spent \$10 million on a campaign to "promote awareness of prostate disease." Winters, *supra* note 4. These ads are not universally well-received. See, e.g., *Miracle Drugs or Media Drugs*, *CONSUMER REP.*, Mar. 1992, at 142 ("[P]romoting drugs in the guise of public education allows the promoters to publicize uses for the drug that have not received FDA approval, and to disregard a drug's side effects . . .").

⁹ See Amy Bernstein, *Prescription Drugs: Pitching Directly to the Patient*, *U.S. NEWS & WORLD REP.*, Jan. 15, 1990, at 46. Some ads that appeared prior to the Rogaine campaign were criticized for crossing the line between information and product-specific selling. See, e.g., *Merrell Dow Anticholesterol Mock-Up TV Spot Citing "Rx Medication" Approaches "Gray Area" Between Education and Drug Ad, FDA Tells Food & Drug Law Institute*, *FOOD DRUG COSM. REP. PRESCRIPTIONS AND OTC PHARMACEUTICALS (THE PINK SHEET)*, Feb. 1, 1988, at 16.

¹⁰ See *infra* part III.B.2.a.

¹¹ "The most common adverse effects [of topical Rogaine use] are local

potential tort claim is minimal, and Upjohn's liability exposure small.

Since Upjohn's initial direct-to-consumer advertising campaign, several other firms have conducted similar campaigns.¹² Extensive direct-to-consumer advertising campaigns have been conducted for Seldane¹³ and Hismanal,¹⁴ two non-sedating antihistamines, and for various brands of anti-smoking "patch" transdermal nicotine delivery systems.¹⁵

The reasons for directly informing potential consumers about these particular drugs are clear. In the case of non-sedating antihistamines, a large market of users of traditional antihistamine medications already exists.¹⁶ The incentive is to inform this market of a new and attractive alternative medication faster than would be possible if the drug companies depended solely on physicians as a conduit of information. The conditions treated by antihistamines¹⁷ often do not require extensive physician involvement, and a patient may see a doctor only infrequently.

For anti-smoking treatments, a large body of potential users exists who, before the introduction of these drugs, might not have considered consulting a doctor to stop smoking. Advertising the drug to physicians would thus be extremely under-inclusive, reaching only those patients already under the care of a doctor for related diseases, but not smokers who have yet to

dermatologic reactions . . . and [are] usually mild." AMERICAN HOSPITAL FORMULARY SERVICE, MISCELLANEOUS SKIN AND MUCOUS MEMBRANE AGENTS 84:36: MINOXIDIL (1989), available in LEXIS, Genmed Library, AHFS File.

¹² Prescription drug advertising spending reached \$200 million in 1992. See Winters, *supra* note 4.

¹³ See TIME, Aug. 12, 1991, at 7-8.

¹⁴ See NEWSWEEK, July 15, 1991, at 10-12.

¹⁵ See TIME, Jan. 25, 1993, at 41-42; TIME, Mar. 15, 1993, at 42-43 (Advertisement for Norplant System contraceptive implants); *id.* at 50 (Advertisement for Cardizem CD, touted as a cheaper alternative to Cardizem).

¹⁶ For example, in 1988, the market for non-sedating antihistamines was over \$180 million. Johnson & Johnson's Hismanal (Astemizole) Is Second Non-Sedating Rx Antihistamine, WKLY. PHARMACY REP. (THE GREEN SHEET), Jan. 9, 1989, at 2.

¹⁷ "Antihistamines are most often used to provide symptomatic relief of allergic symptoms . . ." AMERICAN HOSPITAL FORMULARY SERVICE, ANTIHISTAMINE DRUGS: ANTIHISTAMINES GENERAL STATEMENT (1979), available in LEXIS, Genmed Library, AHFS File.

develop smoking-related symptoms or who do not otherwise see a doctor regularly.

These two categories of drugs have potentially dangerous side effects or drug interactions which complicate the duty to warn. Seldane and Hismanal have been under FDA inquiries which found that users of these drugs are subject to increased risk of heart disease in some circumstances.¹⁸ Similarly, nicotine patches have recently come under FDA scrutiny, as have the ads promoting them.¹⁹ Anecdotal reports tend to show a higher incidence of heart disease among users of the patches who continue to smoke, physician confusion about how to prescribe the patch, failure to accompany the patch with behavioral modification therapy, and confusion among patients as to the proper use of the patches.²⁰

This article argues that because of the lack of FDA regulation specifically addressing direct-to-consumer advertising, state tort law should be used to impose additional requirements on the content of drug advertisements. These state tort requirements can ensure that direct-to-consumer advertisements carry warnings that are specifically designed to convey reasonable warnings to lay users of drugs, not merely the prescribing physicians. Drug manufacturers must design their advertisements carefully, looking not only to FDA advertising regulations, but to common law reasonableness standards to avoid imposition of liability.

II. FAILURE TO WARN DOCTRINE: ELEMENTS OF THE CASE

Although failure to warn cases are often couched in the strict liability language of section 402A of the Restatement (Second) of Torts, in reality the doctrine necessarily involves a measure of negligence-based "reasonableness" testing by a jury.²¹ Thus, the plaintiff must plead and prove: (a) an injury

¹⁸ See *Warning Is Being Issued for the Drug Seldane*, N.Y. TIMES, July 8, 1992, at A20; *Warning Issued on 2d Antihistamine*, N.Y. TIMES, July 21, 1992, at C2.

¹⁹ *Nicotine Replacement Product Direct-to-Customer Ads Are Appropriate Thing to Do; Boxed Label Warning Could Discourage Quit Attempts — AMA Advisory Comm.*, FOOD DRUG COSM. REP. PRESCRIPTION AND OTC PHARMACEUTICALS (THE PINK SHEET), July 20, 1992, at 8.

²⁰ See Elyse Tanouye, WALL ST. J., October 20, 1992, at B5.

²¹ See *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425 (2d Cir. 1969).

(b) caused (c) by the breach (d) of an affirmative duty to warn of the dangerous nature of a product.

A. DUTY

Courts generally hold that a duty to warn arises when it would be unreasonable to market the product without such a warning. *Anderson v. Klix Chem. Co.*²² states that the issue of duty to warn is a negligence inquiry; the relevant question being whether it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a warning. Consistent with the reasonableness core of this standard, manufacturers generally are not required to warn of the danger of an allergic or other unusual reaction to a product unless the risk is shared by a significant number of users.²³

If a defendant does not supply an adequate warning with a product, that product is thereby rendered unreasonably dangerous. Some courts express this rule by stating that without a sufficient warning, strict liability attaches to the sale of the product and the manufacturer is liable for any harm it causes.²⁴ This is not precisely accurate, since the question of whether or not to warn is decided upon reasonableness (i.e., negligence-based) standards.

B. BREACH

The duty to warn may be breached by a complete failure to warn or by a failure to deliver a sufficient warning. A warning may be judged insufficient where it is directed at the wrong recipient or where its substance is inadequate. A substantively sufficient warning is judged on a reasonableness standard, meaning that a reasonably prudent manufacturer would have supplied such a warning on the facts of the present case. The plaintiff must identify a specific danger that should have been the subject of a warning, show the defendant's knowledge of

(holding that comment k to § 402A is an exception to the doctrine of strict liability).

²² 472 P.2d 806, 808 (Or. 1970).

²³ See *C. A. Hoover & Son v. O. M. Franklin Serum Co.*, 444 S.W.2d 596, 598 (Tex. 1969).

²⁴ See, e.g., *Gonzales v. Carmenita Ford Truck Sales, Inc.*, 238 Cal. Rptr. 18 (Cal. Ct. App. 1987).

that danger at the time the warning was or should have been given,²⁵ and show an alternative warning which could have been implemented by the defendant and which would have changed plaintiff's behavior so that he would not have been injured.

C. CAUSATION

The issue of causation is a subject of some controversy in failure to warn litigation. The debate centers upon whether the plaintiff must prove proximate cause (i.e., that given an adequate warning, plaintiff would have modified his action); or cause in fact (i.e., mere evidence of inadequacy of the actual warning given). Opponents of a proximate cause requirement claim that if this proof is required, it will undermine the normative policies behind strict tort liability insofar as the manufacturer will escape liability for injuries caused by a defect (the lack of warning) in his product. Failure to warn, however, is not a pure strict liability theory. A manufacturer is not negligent for failure to warn if the plaintiff's proposed warning would have had no substantive effect on the behavior of its recipients.

III. THE LEARNED INTERMEDIARY RULE

Prescription drug manufacturers are exempt from the duty to warn the end consumer of potential dangers associated with use of a drug. This rule arises out of comment *k* to the RESTATEMENT (SECOND) OF TORTS section 402A.²⁶ Comment *k*

²⁵ Toole v. Richardson-Merrell, Inc., 60 Cal. Rptr. 398 (Cal. Ct. App. 1967).

²⁶ Comment *k* reads:

Unavoidably Unsafe Products. There are some products which in the present state of human knowledge are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.

shields drug manufacturers from strict liability, and forces any analysis of their liability into the realm of negligence.²⁷ Negligence-based liability can take three forms: liability for negligent manufacture, liability for failure to warn properly, or liability for defective product design.

Because of the uncertainty of much drug design, and the fact that even a designer may not know for certain how a drug works (and the inability of a designer to substitute a less dan-

It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

²⁷ A recent commentator claims that comment *k* is not applied to prescription drugs universally. See Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 777-78 n.29 (1990). Without ruling out the possibility that rogue courts will bypass comment *k* and impose strict liability, the case which that Note cites, *Feldman v. Lederle Lab*, 479 A.2d 374 (N.J. 1984), *cert. denied*, 112 S. Ct. 3027 (1992), is not a strict liability case, whatever the court may claim. Courts often claim strict liability status for comment *k* analysis. This doctrinal confusion probably springs from the fact that comment *k* imposes a negligence-based test as a threshold question determining the applicability of strict liability. The court in *Feldman* stated that "drug manufacturers have a duty to warn of dangers of which they know or should have known on the basis of reasonably available knowledge." *Id.* at 389. The use of "reasonableness" language is the keystone of negligence-based inquiry. The court further states that if this test is not met, strict liability will apply. *Id.* Close analysis of the concept of strict liability will show that, if true strict liability were used here, the initial reasonableness question would never be asked. Strict liability abandons the questions of duty and breach found in negligence analysis and focuses exclusively on defect and causation. One could argue that the *Feldman* test is strict liability insofar as it defines as "defective" a drug which carries an unreasonable warning, then applies strict liability to those drugs. This analysis is functionally equivalent to stating that all drugs that carry insufficient warnings are unreasonably dangerous, which is a negligence-based analysis. This distinction is meaningless because of the fact that either way, the true test of liability is the first step in the analysis, which is a reasonableness inquiry, not strict liability.

gerous alternative),²⁸ courts traditionally have not applied defective design analysis to prescription drugs.²⁹

Comment *k* expressly preserves manufacturing defect and warning theories of liability in its qualification that to avoid liability a product must be "properly prepared, and accompanied by proper [physician-directed] directions and warning."³⁰ This article will focus on liability for failure to warn, as that is the doctrine which has been expressly modified upon consideration of the problems raised by prescription drugs.³¹

A. CONTENT OF A LEGALLY SUFFICIENT WARNING

The duty to warn³² is imposed to "apprise the user of a

²⁸ This characteristic may be changing with advances in our understanding of how drugs work at biochemical levels. The law may or may not keep up with technological developments. See James A. Henderson & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512 (1992) (arguing for no design review for prescription drugs). To the extent that courts are slow to adopt design liability for a product that is susceptible of design change, manufacturers will be the beneficiaries of a windfall in the form of liability avoidance.

²⁹ The American Law Institute has recently decided to revise the Restatement of Torts. Professors James Henderson and Aaron Twerski have been named as the reporters for the Products Liability provisions. Coincidentally, Henderson and Twerski recently published a proposed revision of § 402A, intended to cut through the years' accumulation of judicial glosses on the text of the original 402A and its comments and to create a "true" restatement of the state of the law. Professors Henderson and Twerski reject most litigation of design defect issues in drug litigation, arguing that failure to warn doctrine encompasses the vast majority of the cases where design review would be useful.

[S]o long as a group exists for whom the drug in question is the drug of choice, then the issue of design has no place in the applicable liability law To warn adequately [of the dangers of an unreasonably designed drug], the manufacturer would have to inform the medical profession either that its product is useless or that a fully acceptable alternative to the drug exists that has all the benefits but fewer of the detriments of the drug in question.

Henderson & Twerski, *supra* note 28, at 1538-39.

³⁰ RESTATEMENT, *supra* note 26, § 402A cmt. k. Liability for negligent manufacture is also irrelevant to direct-to-consumer advertising. A product negligently manufactured will expose its sellers to tort liability regardless of how it is advertised.

³¹ See *supra* note 26 and accompanying text.

³² The duty to warn is imposed by RESTATEMENT (SECOND) OF TORTS § 388 (1965). I recognize here a distinction between warnings, which are designed

danger which he is not aware of, so that he can protect himself against it."³³ There is no duty to warn of obvious risks.³⁴ The content of an appropriate warning is an issue of fact for a jury.³⁵ The precision and clarity required varies with the severity of potential danger and the commonness and familiarity of the product. On this analysis, warnings about prescription drugs are generally subject to a quite high standard, since the potential for harm is almost unlimited, and the average consumer cannot be expected to know much, if anything, about the potential biological effects of the product. "In the case of extremely dangerous products, the supplier may be required to go to considerable lengths to inform the required persons of danger, and may be held liable if it engages in other sales activity which has the effect of offsetting the otherwise sufficient warning."³⁶

B. WHO GETS WARNED: THE LEARNED INTERMEDIARY RULE

1. *The Rule*

Given that a duty to warn arises in connection with prescription drugs, the next logical question is: who can or should be the subject of a legally sufficient warning?

to help a consumer recognize and avoid, if possible, an inherent danger in the product; and instructions, which are designed to teach a consumer how to use a product so as to avoid unnecessary danger. Because of the nature of drugs as essentially unalterable quantities, the relevant consumer choice informed by warning is often simply whether the potential benefits outweigh the known risks. *But see* Henderson & Twerski, *supra* note 28

³³ *Lister v. Bill Kelley Athletic, Inc.*, 485 N.E.2d 483, 487 (Ill. App. Ct. 1985).

³⁴ *See* *Jamieson v. Woodward & Lothrop*, 247 F.2d 23 (D.C. Cir.), *cert. denied*, 355 U.S. 855 (1957).

³⁵ *Miles v. Kohli & Kaliher Assoc., Ltd.*, 917 F.2d 235, 246 (6th Cir. 1990) ("The fact finder may find a warning to be unreasonable, hence inadequate, in its factual content, its expression of the facts, or the method or form in which it is conveyed.") (quoting *Seley v. G.D. Searle Co.*, 423 N.E.2d 831, 837 (Ohio 1981)).

³⁶ Allan E. Korpela, Annotation, *Failure to Warn as Basis for Liability under Doctrine of Strict Liability in Tort*, 53 A.L.R. 3D 239, 245 (1973); *see also* *Sterling Drug v. Yarrow*, 408 F.2d 978 (8th Cir. 1969) (warning insufficient because of the overly optimistic and salesman-like tone of the warning letter).

The general rule is that the end user is entitled to a warning about the dangers associated with the product,³⁷ consistent with the policy of encouraging informed consent. Courts have been willing to modify this rule, however, in cases where the end user is not in a position to use or benefit from the information contained in a legally sufficient warning. Thus, in *Stevens v. Cessna Aircraft Co.*,³⁸ the manufacturer of an airplane that crashed was not required to have warned the individual passengers about the load capacity of the plane. The court reasoned that the load of the aircraft depends upon too many factors for the individual passenger to be able to use the information effectively to mitigate the risk faced. The airline served as a "learned intermediary" who, because of its superior ability to make use of the information, is a more sensible target for the legal duty to warn.

The learned intermediary rule is also widely applied to prescription drug cases. The rationale for not requiring warnings to individual patients is that the patient is not capable of effectively making use of the information given, and the physician is better able to make an informed choice about the balance of risks and benefits to be gained from use of the drug.³⁹

Professor Schwartz has identified four separate rationales for the learned intermediary rule.⁴⁰ First, physicians ultimately decide whether and what drug to prescribe based on available alternates. Second, physicians are already legally obligated to convey risk/benefit information to patients under the doctrine of informed consent, so such a duty on the part of the drug manufacturer to also convey information to patients would be redundant. Third, providing information to the patient outside of the traditional doctor-patient relationship (such as through direct-to-consumer advertising) could interfere with that rela-

³⁷ See, e.g., *Griggs v. Firestone Tire & Rubber Co.*, 513 F.2d 851 (8th Cir. 1975) (requiring manufacturers and suppliers to provide a warning on a product so that it would reach the ultimate consumer); see also RESTATEMENT (SECOND) OF TORTS § 388 (1965).

³⁸ 170 Cal. Rptr. 925 (Cal. Ct. App. 1981).

³⁹ In order to use the learned intermediary exception, however, a drug manufacturer must have provided a legally adequate warning to the physician. See *Fornoff v. Parke Davis & Co.*, 434 N.E.2d 793 (Ill. App. Ct. 1982).

⁴⁰ Teresa M. Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 830 (1991).

tionship by deterring patients from following their doctors' advice.⁴¹ Fourth, providing this information to patients has too high a cost or cannot be adequately conveyed by labeling.

These factors, however, also support the creation of an exception to the learned intermediary rule for direct-to-consumer advertising. First, direct-to-consumer advertising, while it does not remove physicians from their position of control in prescribing drugs, clearly influences the balance of power in the physician-patient relationship. A physician confronted with a patient who is informed about the treatment alternatives will probably give substantial weight to that patient's desires when making treatment decisions. While this clearly should not lessen the duty physicians have toward their patients to choose the best treatment alternative, it can support increasing the duty owed by drug manufacturers. Physicians may not be aware of the sources of their patients' information, and so may not be able to effectively counteract unreasonable expectations which advertising may create. Imposition of a duty to warn on manufacturers minimizes the dangers of unrealistic portrayals of a drug's benefits.

Second, while physicians are obligated to convey risk/benefit information, limitation of that duty to physicians makes more sense when physicians are the sole source of a patient's information about a drug. If a drug manufacturer has no duty to supplement direct-to-consumer advertisements with warning information, advertisements weigh into the patient's mix of information wholly on the positive side, and may tip the balance regardless of an otherwise perfectly adequate warning conveyed by a physician.

Third, although interference with the physician-patient relationship is a concern, patient warnings in drug advertising

⁴¹ This rationale presumes a paternalistic model of the doctor-patient relationship, in which "the physician presents the patient with selected information that will encourage the patient to consent to the intervention the physician considers best The paternalistic model assumes that there are shared objective criteria for determining what is best." Ezekiel J. Emanuel & Linda L. Emanuel, *Four Models of the Physician/Patient Relationship*, 267 JAMA 2221, 2221 (1992). In contrast, one of the premises of both the informed consent and failure to warn doctrines is that the doctor and the patient share responsibility for decisions affecting treatment. Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633, 652-54 (1986). These doctrines thus seem to rest on a "deliberative" or "interpretive" model of the doctor/patient relationship. Emanuel & Emanuel, *supra*, at 2221-22.

are unlikely to have the deterrent effect envisioned by Professor Schwartz. Direct-to-consumer advertising is fundamentally advertising, designed to create a positive image of the product in the mind of the consumer. The warnings which FDA regulation and tort law would require will supplement the positive aspects of the advertising, but will prevent blatant puffery and insupportable claims of efficacy without destroying the character of the advertising. Further, any drug which cannot be discussed without including a warning likely to deter an average user is not the sort of drug likely to be the subject of direct-to-consumer advertising.

Fourth, Professor Schwartz claims that provision of warnings directly to patients either has too high a cost or cannot be adequately conveyed by labeling. One of the functions of tort law is to ensure that product cost reflects total societal cost. Refusal to impose a duty to warn on direct-to-consumer advertising would alter the total mix of information that patients receive, and would skew their treatment choices. This would provide a windfall to drug manufacturers because they would not be faced with liability for injuries caused by their advertisements. The substance of the advertisements would also be altered, since manufacturers would have an incentive to present as favorable a portrayal of their product as possible without crossing the line of fraud. In short, the duty to warn, while it imposes costs on manufacturers in the short term, allows a more realistic assessment of the true costs of direct-to-consumer advertising.

2. *Exceptions*

There are two major exceptions to the learned intermediary rule. The first applies to birth control pills, the second to mass clinical inoculations. As this part will show, both of these exceptions are consistent with Professor Schwartz's policies and with application of state tort law to direct-to-consumer advertising.

a. *Birth Control*

In *MacDonald v. Ortho Pharmaceutical Corp.*,⁴² plaintiffs sued the manufacturer of birth control pills for injuries. The

⁴² 475 N.E.2d 65 (Mass.), *cert. denied*, 474 U.S. 920 (1985).

jury returned a verdict for plaintiffs, and Ortho appealed on the grounds that it did not owe a duty to the end user of the drug, since it was a prescription item and Ortho had sufficiently warned the medical community. The appellate court upheld the jury verdict on three grounds. First, the court held that the decision to use birth control pills was not analogous to the decision to use other drugs. The patient generally decides whether to use the birth control pill based on personal lifestyle grounds rather than on medical necessity grounds, and the doctor is consulted only to determine the optimum dosage. Second, after the initial prescription, the patient has minimal contact with the physician, and thus minimal opportunity to ask questions or become informed through the traditional physician/patient channel. Third, the FDA closely regulates the use of birth control pills with the stated goal that the end user be "informed by comprehensible warnings of potential side effects."⁴³

b. *Mass Inoculations*

The second exception to the learned intermediary rule is for inoculations performed outside the "normal" doctor-patient relationship (i.e., in a public clinic, often in connection with state-mandated vaccination programs).⁴⁴ The rationale here is similar to the birth-control exception: where there is no direct physician control over the procedure, and where the decision is not made for each individual patient by a doctor, the duty to warn devolves to the manufacturer.⁴⁵

These two exceptions to the learned intermediary rule illustrate the value courts place on patient information. Where the

⁴³ *Id.* at 69.

⁴⁴ See, e.g., *Reyes v. Wyeth Lab.*, 498 F.2d 1264 (5th Cir. 1974) (concluding that a defendant manufacturer has a duty to directly warn individual vaccinees); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121 (9th Cir. 1969) (applying strict liability to vaccine manufacturers). But see National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-14(a) (Supp. II 1990) (partially overturning the mass immunization exception and establishing a no-fault recovery system). For a general discussion on mass immunization cases, see Robert M. McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943 (1988).

⁴⁵ At least one case holds that this duty is delegable, and that the manufacturer can satisfy it by contractually obligating another to warn the end user of the relevant dangers. *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1365 (3d Cir.), cert. denied, 113 S. Ct. 463 (1992).

policy concerns supporting the learned intermediary rule, as noted by Professor Schwartz, do not apply — the physician does not control the decision-making process and flow of information, nor is there an ongoing doctor-patient relationship — courts will circumvent the learned intermediary rule and impose the duty to warn the patient directly on the manufacturer. Both of these effects are present to a degree in direct-to-consumer advertising.

IV. FDA REGULATION OF PRESCRIPTION DRUG ADVERTISING

The FDA regulates drug packaging and labeling.⁴⁶ Both the FDA and the courts interpret this mandate to include regulation of virtually all public statements made about a drug by its manufacturer, including advertising.⁴⁷ Currently, the FDA has promulgated two requirements for providing warnings about prescription drugs, requiring a package insert and a "brief summary." These requirements do not specifically address direct-to-consumer advertising,⁴⁸ and as a result, do not adequately protect consumers.

First, the FDA requires a package insert as part of a drug's packaging.⁴⁹ The package insert requirements provide the most comprehensive analysis of a drug's indications and risks. This information, including a description of the drug, its clinical pharmacology, indications and usage, contraindications, warnings, precautions, adverse reactions, drug abuse and dependence, overdosage and dosage and administration information, is clearly designed for the use of the prescribing physician. A lay consumer trying to make effective use of this information would be deterred by both the sheer amount and the technical

⁴⁶ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321(k),(m) (1988).

⁴⁷ See *Prohibited Acts*, Food Drug Cosm. L. Rep. (CCH) ¶ 4016 (1990) ("Courts . . . have not hesitated [to call advertising 'labeling,'] since the FDC Act definition could have excluded matter that is advertising but did not."); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(n) (1988) (imposing "brief summary" requirement for prescription drug advertising).

⁴⁸ See Elisabeth Rosenthal, *Drug Makers Set Off Bitter Debate With Ads Aimed Directly at Patients*, N.Y. TIMES, March 3, 1991, at I34 ("Although the law now governs all prescription drug advertising, it was written at a time when doctors were the only audience . . ."); Food Drug Cosm. L. Rep. (CCH) ¶ 70191 (1990) ("[T]here is no statutory distinction between professional advertising and advertising directed to consumers.").

⁴⁹ See 21 C.F.R. § 201.100(d)(2) (1992).

language of the package insert.⁵⁰ Another drawback is that this type of warning, because of its length and complexity, is very difficult to append to a broadcast or print advertisement.

Second, the FDA generally requires that any advertisement of a drug carry a "brief summary"⁵¹ of the information in the package insert. "The brief summary sets out the drug's adverse experience profile, contraindications, warnings, and precautions, as well as the indications for use. The other sections required in the package insert, such as pharmacology and dosage, are not required in the brief summary."⁵² Although the brief summary requirement is obviously problematic for broadcast advertisements, at least one solution has been implemented. The Lifetime cable television network, which airs health-related segments aimed at medical professionals, has a policy of airing the brief summary information for all the advertisements it carries late at night after its regular programming.⁵³ The supporting rationale is that one can set a VCR to record this information, and then view it at one's leisure.⁵⁴ This practice, although possibly reasonable for advertisements aimed at medical professionals, probably would not be considered reasonable in the context of a warning directed at a lay consumer.⁵⁵

Inclusion of the brief summary information is easier for print media advertisements, since the information can simply be printed alongside or on the reverse of the advertisement. Still, there are two obvious complications. First, even the brief

⁵⁰ Indeed, the drug as dispensed to the consumer generally will not contain a package insert, but only directions given by the prescribing doctor or dispensing pharmacist. If the drug includes in the package insert the information required, the FDA does not require the manufacturer to ensure that the drug label bears "adequate directions for lay use." *Special Requirements for Prescription Drugs*, Food Drug Cosm. L. Rep. (CCH) ¶ 70,177 (1990). Clearly, this exception codifies in regulation the learned intermediary rule.

⁵¹ 21 C.F.R. § 202.1(e)(1) (1992); see also David A. Kessler & Wayne L. Pines, *The Federal Regulation of Prescription Drug Advertising and Promotion*, 264 JAMA 2411 (1990).

⁵² 21 C.F.R. § 202.1(e)(1) (1992).

⁵³ Kessler & Pines, *supra* note 51, at 2412-15.

⁵⁴ *Id.*

⁵⁵ See *Gonzales v. Carmenita Ford Truck Sales, Inc.*, 238 Cal. Rptr. 18, 22 (Cal. Ct. App. 1987) ("Where . . . a product is unreasonably dangerous absent a warning, . . . strict liability in tort will attach if appropriate and conspicuous warning is not given." (quoting *Burke v. Almaden Vineyards, Inc.*, 86 Cal. App. 3d 768, 772 (1978)) (emphasis added)).

summary information, to comply with FDA regulations, must be quite complex. To be an adequate warning under common-law tort doctrine, the text must be comprehensible to the consumer; that is, it must be able to convince the average consumer to modify her behavior.⁵⁶

Second, the tone or character of the entire communication can effectively contradict the information in the warning. In *Yarrow v. Sterling Drug*,⁵⁷ the plaintiff's injury was a side effect of the drug Aralen. The manufacturer knew of the side effects, but the side effects had not yet been widely reported in the medical literature. To inform prescribing physicians of the dangers, the manufacturer sent "Dear Doctor" letters to over 200,000 physicians. The court held that, although the letter did describe the potential side effects of the drug, the effectiveness of the warning was eclipsed by the overly optimistic, salesman-like tone of the letter. Similarly, an inherent quality of advertisement is that it is intended to present a positive picture of the effects of the product. Thus, although FDA regulations may ensure that physicians receive adequate information, the regulations are inappropriate when applied to direct-to-consumer advertising to ensure consumers receive complete information on a prescription drug.

V. PREEMPTION OF STATE TORT LAW BY FDA REGULATION?

A. FDA REGULATION AND PREEMPTION OF STATE TORT LAW

Federal regulations, as well as federal statutes, can preempt state law.⁵⁸ Preemption may be either expressly intended by Congress⁵⁹ or implied from the regulatory context. If not

⁵⁶ See *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass.), *cert. denied*, 474 U.S. 920 (1985) (finding a highly technical warning inadequate because the consumer did not understand the practical dangers described).

⁵⁷ 263 F. Supp. 159 (D.S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969).

⁵⁸ *Hillsborough County, Fla. v. Automated Medical Lab.*, 471 U.S. 707, 713 (1985). The doctrine of federal preemption arises from the Supremacy Clause of the United States Constitution. U.S. CONST. art. VI.

⁵⁹ *Wisconsin Pub. Intervenor v. Mortier*, 111 S. Ct. 2476, 2481 (1991); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); see also, e.g., 29 U.S.C. § 1144(a) (1988) (express preemption clause in Employment Retirement Income Security Act, stating that ERISA "shall supersede any and all State

intended, preemption may still be triggered if state law contravenes federal policies. Implied preemption occurs in two circumstances: (1) when federal action in a given field of law so completely occupies the field as to foreclose state action;⁶⁰ or (2) when the nature of the concurrent state and federal regulation causes conflict between state and federal interests or makes concurrent compliance impossible.⁶¹

B. CASE LAW DOES NOT SUPPORT PREEMPTION

The Federal Food, Drug and Cosmetic Act does not expressly preempt state tort law in the labeling context.⁶² Courts must therefore justify preemption, if at all, based on implied preemption doctrine. The traditional rule in tort cases is that federal regulation provides a floor, not a ceiling, for product safety, and so does not preempt concurrent state regulation through tort law.⁶³ At least two federal courts have refused to allow the defense of preemption in failure to warn cases involving vaccines. Both *Abbott v. American Cyanamid Co.*⁶⁴ and

laws insofar as they . . . relate to any employee benefit plan . . .").

⁶⁰ Modern courts rarely find preemption on occupation grounds. Wisconsin Pub. Intervenor, 111 S. Ct. at 2481-82 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); see generally Note, *The Preemption Doctrine: Shifting Perspectives in Federalism and the Burger Court*, 75 COLUM. L. REV. 623 (1975).

⁶¹ See *California v. Federal Energy Regulatory Comm'n*, 495 U.S. 490 (1990); Wisconsin Pub. Intervenor, 111 S. Ct. at 2482; *Jones*, 430 U.S. at 526; *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1940).

⁶² 1 Food Drug Cosm. L. Rep. (CCH) ¶ 4007 (Apr. 1, 1991) (noting that the only express preemptions relate to food and medical devices). For an example of medical device preemption analysis, see *Stamps v. Collagen Corp.*, No. 92-2084, 1993 WL 43588 (5th Cir. 1993) (to be reported at 984 F.2d 1416); Paul J. Martinek, *Implant Suit Preempted; Medical Device Claims Stymied by FDA Rules*, MASS. L. WKLY., Jan. 25, 1993, at 1.

⁶³ Teresa M. Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1135-36 (1988); *Roberts v. May*, 583 P.2d 305, 308 (Colo. Ct. App. 1978); see also 1 Food Drug Cosm. L. Rep. (CCH) ¶ 4007 (Apr. 1, 1991) ("[S]tate laws that set stricter rules than are established under the federal laws are not preempted . . ."). While compliance with federal regulations is not a complete defense, the jury may be allowed to expressly weigh it along with other factors in determining liability. See Schwartz, *supra* note 40, at 1136.

⁶⁴ 844 F.2d 1108 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988).

*Graham v. Wyeth Lab.*⁶⁵ held that state tort law provided a cause of action regardless of fairly comprehensive federal regulation.

In *In re Tetracycline Cases*,⁶⁶ plaintiffs ingested the drug tetracycline during periods of tooth development. Tetracycline was known to cause tooth discoloration, and the FDA had promulgated a warning required to accompany the drug. The defendant drug manufacturers argued unsuccessfully that, because of this regulation, state tort law claims were preempted. Specifically, defendants argued that manufacturers could not comply with the requirements of both federal regulation and state tort doctrine without destroying the uniformity that the federal regulations were designed to achieve. The court held that state tort regulation of manufacturer warnings was not inconsistent or in conflict with federal regulation, because the manufacturer could take action to comply with the state requirements, which would supplement, not conflict with, the FDA warning requirements. The court noted that "this and other federal courts have . . . ruled that FDA regulation does not preempt . . . the duty to warn of product risks . . . [or] the duty not to place unreasonably dangerous products into commerce."⁶⁷ This decision implicitly supports the "floor" theory of preemption. A state can require additional warnings without impinging upon a federal interest, so long as it does not expressly invalidate a specific federal requirement.

C. THE POLICY ARGUMENTS AGAINST PREEMPTION

Preemption of state tort law by FDA regulation is not only rejected by the case law. Normative concerns, including principles of equity, communitarianism, and distributive justice, require a compensation mechanism for injured consumers of prescription drugs. Failure to warn litigation is an important component of this mechanism.

Several recent commentators⁶⁸ make the normative case

⁶⁵ 666 F. Supp. 1483 (D. Kan. 1987).

⁶⁶ 747 F. Supp. 543 (W.D. Mo. 1989).

⁶⁷ *Id.* at 550.

⁶⁸ See, e.g., John F. Del Giorno, Comment, *Federal Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing on State Court Jury Decisions in Products Liability Cases*, 22 J. MARSHALL L. REV. 629 (1989); Note, *A Question of Competence: The Judicial Role in the Regulation*

for deferring to the judgment of the FDA regarding the safety of prescription drugs. While this proposal may make sense in the context of drug approval, it makes far less sense when applied to direct-to-consumer advertising. Rather, the need for outside review of direct-to-consumer advertising, the competence of juries to determine community standards, and the market failure remedied by tort all support the need for state tort law remedies.

1. *Need for Substantive Outside Review of
Direct-to-Consumer Advertising*

First, there is persuasive data that, issues of expertise aside, the administrators of the FDA will do no better job than the post hoc enforcers of the courts. A recent study of drug advertisements showed that ninety two percent of the examined advertisements contained potential violations of the FDA guidelines, and that the average advertisement contained four potential violations.⁶⁹ This situation is exacerbated by the fact that, absent special circumstances, drug advertisements need not be submitted to the FDA for approval prior to publication.⁷⁰

Further, in 1988, the FDA required Sandoz Laboratories to pull one of its newspaper advertisements due to inaccurate claims which had been overlooked when the FDA first approved the advertisement.⁷¹ If compliance with FDA procedures acted as a bar to state tort liability, then a repeat of this error would

of *Pharmaceuticals*, 103 HARV. L. REV. 773 (1990) [hereinafter *Question of Competence*]; Gregory C. Jackson, Comment, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199 (1992).

⁶⁹ See *Medical Journal Rx Drug Ad Survey Finds Four Potential FDA Violations Per Ad; Physicians/Pharmacists Surveyed Feel 92% of 1990 Ads May Be In Violation*, FOOD DRUG COSM. REP. PRESCRIPTION AND OTC PHARMACEUTICALS (THE PINK SHEET), June 1, 1992, at 1.

⁷⁰ See 21 C.F.R. § 202.1(e)(1) (1992). Advertisements must be submitted for prior approval if the use of the drug may cause fatalities or serious injury, and information about this possibility has not been widely publicized in the medical literature. 21 C.F.R. § 202.1(j). See generally Food Drug Cosm. L. Rep. (CCH) ¶ 70191.

⁷¹ Michelle D. Ehrlich, Comment, *Doctors Can Just Say No: The Constitutionality of Consumer-Directed Advertising of Prescription Drugs*, 12 HASTINGS COMM. & ENT. L.J. 535, 559 (1990) (citing Patricia Winters, *Why the FDA Made Sandoz Pull Drug Ad*, ADVERTISING AGE, February 29, 1988, at 70).

sacrifice compensation of an injured plaintiff to ideals of efficiency.⁷² These incidents show that there is a need for judicial action to supplement FDA policing of its guidelines and regulations.

A related argument is the problem of agency capture. Capture is a phenomenon by which the industry, such as the pharmaceutical industry, that an agency purports to regulate actually exerts de facto control over the policy making of the agency. Once an agency is captured by the industry it regulates, agency policy makers and adjudicators have incentives to defer to the interests of the industry rather than protecting the interests of consumers. While this article does not charge the FDA with capture by the pharmaceutical industry, judicial review of companies' actions independent of and supplemental to agency action guards against capture by lessening the unilateral power of the agency, making capture less attractive to the industry.

2. "Judicial Incompetence"

A common refrain in modern critiques of the tort system is judicial incompetence in dealing with complex scientific issues.⁷³ Proponents of judicial incompetence argue that judges and juries, being mere lawyers and laymen, cannot reliably and efficiently dispense justice when doing so requires mastery of complex facts. Since the FDA is staffed with experts in pharmacology, courts should defer to the regulations and decisions of

⁷² If Congress desired to expressly preempt state tort law, equity, and at least one commentator, would insist that tort liability be supplanted by an alternate compensation scheme. See Gregory C. Jackson, Comment, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199 (1992) (proposing a model, to be funded by the industry (read, funded by consumers) based on the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 (1988), and the Swedish Pharmaceutical Insurance program). Note, however, that the tort system shares this program's normative goal of cost-spreading. See *infra* part V.C.2.

⁷³ Cf. PETER HUBER, *GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM* (1991) (arguing that while judges are perfectly capable of addressing scientific issues, expert witnesses are instead paraded through the courtroom, serving only to convolute the issues and confuse the jury); *Question of Competence*, *supra* note 68 (arguing that while the judiciary should defer to the FDA's institutional superiority, the judiciary must ensure that the FDA has sufficient information on which to base its decision).

the FDA in matters relating to the manufacture and sale of drugs.

This argument does not adequately describe failure to warn litigation as a means for judicial review of direct-to-consumer advertising. In failure to warn litigation, unlike other strict liability litigation, the role of the jury as nonscientific arbiters of community standards is pronounced because a fundamental negligence inquiry exists at the heart of failure to warn litigation.⁷⁴ Juries in failure to warn litigation are not asked to evaluate the scientific merits of competing alternative designs as in design defect litigation, nor are they faced with the complex statistics and probability often found in manufacturing defect litigation. Instead, the central inquiry in failure to warn litigation is the reasonableness of the warning actually given, and its effects on the hypothetical "reasonable person." For this task, the jury is better suited than the expert agency. Jury members do not bring the a priori knowledge of the expert to their evaluation, but instead import true community standards of the meaning and reasonableness of warnings.

The use of juries also rests on a solid theoretical foundation, which relies on a republican theory of human nature and law that competes with the liberal model implicit in judicial incompetence arguments.⁷⁵ This theory holds that use of the jury provides both the jurors and the participants in litigation with a sense of being connected with the community in which the litigation is taking place. This should ideally lead to a heightened sense of duty to the community and participation in the polity, both of which are valid normative goals. In contrast, the judicial system envisioned by critics of the tort system seems singularly focused on the "efficiency" of the system and on the result as between the two litigants as atomized individuals with no sense of the effects of the judgment on the social fabric surrounding the decision. A communitarian or republican would charge that this system is based on an inferior conception of human nature and society and should not be encouraged. Tort law provides a sense of justice between the parties and between the community of consumers and the manufacturer that is not available in a sterile, efficient, "scientific" agency proceeding.

⁷⁴ See *infra* note 27.

⁷⁵ See, e.g., *Question of Competence*, *supra* note 68.

3. *Tort as Cure for Market Failure*

A fundamental justification for the tort system is its redistributive and allocative justice effect. The tort system operates to cure market failure by ensuring that products are marketed at a price that truly reflects their societal cost. If a drug causes injury to a significant portion of its target market, leaving those injured users as an externality whom the manufacturer has no incentive or duty to make whole, this creates an injustice and artificially lowers the price for the remaining customers. Drugs may have life-saving properties and thus represent a social good in and of themselves. If there is a social good to be obtained, equity demands that society as a whole bear the cost, not the subset of society representing the unfortunate injured.

Some drugs, while possessing therapeutic merit, perhaps cannot be profitably sold on the market without incurring liability because of injuries to some users. This is the paradigm cited by "reformers" of the tort system.⁷⁶ The appropriate mechanism for making these drugs available is government action, either in the form of limited profit margins, limited punitive damages or direct subsidy to the drug companies. Whatever the mechanism, it must not hide the true costs of the product behind the uncompensated injury of innocent consumers.

The tort system, while spreading the costs of injuries caused by a drug among the total pool of users of that drug, also serves a limiting function. The costs of litigation, apart from recovery paid to plaintiffs, are a transaction cost of the policing mechanism of tort liability. While a perfectly "frictionless" system, free of all transaction costs, is the ideal, it rarely exists outside the writings of Richard Posner or Richard Epstein.

At least one commentator proposes limiting judicial involvement in drug litigation to superficial review of FDA actions governed by principles of administrative law.⁷⁷ This system would also carry its own costs. The common law rule that FDA regulations provide only a floor, not a ceiling, for required warning minimizes litigation over the mechanisms of the FDA decision-making process. If tort recovery is limited or foreclosed, every injured plaintiff will simply remake her claim into a claim against the FDA for improper administrative procedure.

⁷⁶ See 103 HARV. L. REV. 773, *supra* note 68, at 774-45.

⁷⁷ See generally 103 HARV. L. REV. 773, *supra* note 68.

This will increase the FDA's cost of doing business, as well as increase the costs of drug review to *all* manufacturers, not only those who use unreasonable advertising. If the costs do not devolve to manufacturers, they will be charged to taxpayers, and so become yet another externality or subsidy driving down the price of the product at no cost to the manufacturer. This spreads the cost of doing business over a larger pool, but is difficult to justify unless one posits that all manufacturers will eventually have to face litigation, and so a common pool of contributions to litigation costs is beneficial.

CONCLUSION

This article has presented regulatory law, case law and normative policies favoring imposition of tort liability on manufacturers who advertise directly to consumers without carefully considering the capacity of their audience to make a rational, considered decision to accept the risks of using an advertised drug. It should sound a cautionary note to manufacturers flush with the success of recent advertising campaigns to carefully calculate the benefits of the additional audience against the potential tort liability exposure. Compliance with current FDA regulations is insufficient, since those regulations do not explicitly consider the special problems facing direct-to-consumer advertising, particularly the problem of adequately conveying warning information without compromising the purpose of the advertisement.

Careful screening of direct-to-consumer advertising preserves the virtue of increased information to consumers while also safeguarding the role of the physician in the decision making process and, hopefully, lessening the inherent bias in favor of glowing portrayals of drugs and encouraging balanced depictions of the costs and benefits of the products.

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